



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 20 1998 3382 '98 NOV 25 P2:23

Gale Bensussen
President
Leiner Health Products
901 E. 233rd Street
Carson, California 90745-6204

Dear Sir/Madam:

This is in response to your letters of November 10, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Leiner health Products is making the following claims, among others, for the following products:

Tree of Life® Fenugreek

“...soothe irritated tissues”

Tree of Life® Herbal Water Tablets

“...reduce excess body water”

Tree of Life® Cranberry

“...minimize undesirable adhesions...”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely, gastrointestinal disorders, fluid retention, and urinary tract pathogens. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

r/d:HFS-456:RMoore:11/20/98

Init:GCF-1:DDorsey:11/20/98

f/t:HFS-456:rjm:11/20/98:docname:62368.adv:disc33



11/14/98

November 10, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Soothing Herb for Digestion

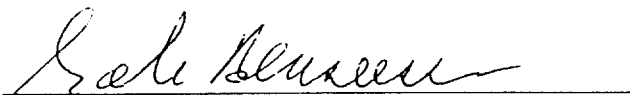
Fenugreek contains mucilage, a compound that becomes gelatinous in the stomach and may soothe irritated tissues. Fenugreek provides nutritional support for the digestive system.

on the following product:

Tree of Life® Fenugreek

Very truly yours,

Leiner Health Products


Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Manager of Regulatory Affairs

62368



11/19/98

November 10, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Supports a Healthy Urinary Tract

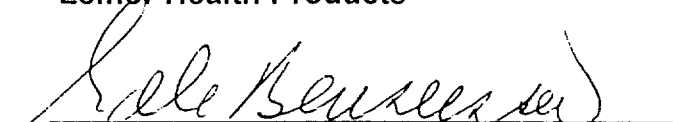
Provides a special combination of traditional herbs which have historically been used to help maintain urinary tract health and reduce excess body water.

on the following product:

Tree of Life® Herbal Water Tablets

Very truly yours,

Leiner Health Products


Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Manager of Regulatory Affairs

62368



November 10, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Promotes a Healthy Urinary Tract

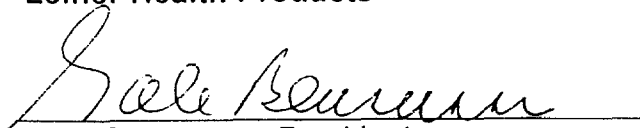
Cranberry juice has been used historically to help maintain normal function of the urinary tract. Constituents naturally present in cranberries minimize undesirable adhesions to the wall of the bladder. Tree of Life Cranberry concentrate capsules provide the same natural acidity found in cranberry juice without added sugar, calories or preservatives.

on the following product:

Tree of Life® Cranberry

Very truly yours,

Leiner Health Products


Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs
William Cochran, Manager of Regulatory Affairs

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